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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,860	07/23/2003	Dale N. Larson	36373-012	7992
7590		12/11/2007		
Sonia K. Guterman, Esq. Lawson & Weitzen, LLP Suite 345 88 Black Falcon Avenue Boston, MA 02210-2414				
			EXAMINER	
			BOWERS, NATHAN ANDREW	
			ART UNIT	PAPER NUMBER
			1797	
			MAIL DATE	DELIVERY MODE
			12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/625,860

Applicant(s)

LARSON ET AL.

Examiner

Nathan A. Bowers

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 3-16 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-16 and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 October 2007 has been entered.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1, 3-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frondoza (US 20050147959) in view of Robinson (US 6890740).

Frondoza discloses an apparatus for intermixing small objects with a liquid comprising a plurality of receptacle wells (Figure 1:3) containing the small objects. Each of the wells has a lower portion (Figure 1:4) that is permeable to permit the flow of liquid therethrough. A vessel (Figure 1:5) containing a solution is also provided, as well as means for repeatedly inserting the receptacles into the solution held in the vessel. The receptacle can then be withdrawn to cause the liquid to flow outwardly through the lower portion while retaining the small objects. This is disclosed in paragraphs [0037]-[0052] and [0064]-[0073]. Specifically, Frondoza teaches in paragraphs [0051] and [0052] that the small objects comprise cells cultured upon microcarriers. Paragraphs [0064]-[0073] further indicate that the cells are subjected to pharmaceuticals in order to study their affects on the activity and health of the cells. Frondoza, however, does not expressly indicate that a portion of the side walls of the receptacle is permeable.

Robinson discloses an apparatus for intermixing objects and a liquid comprising at least one receptacle (Figure 2:24) having sides and a bottom. In one embodiment (See Figure 1), the bottom and the sides of the receptacle are permeable. In another embodiment (See Figure 2), only the bottom of the receptacle is permeable. This is disclosed in column 3, lines 10-35.

Frondoza and Robinson are analogous art because they are from the same field of endeavor regarding filtering mechanisms.

At the time of the invention, it would have been obvious to modify the apparatus of Frondoza so that the receptacle includes a side wall portion that is permeable and a side wall

portion that is not permeable. Frondoza already teaches the use of impermeable side walls, whereas Robinson indicates that the use of permeable side walls (in Figure 1) are known in the art as well. Therefore, it would have been apparent to modify the porosity of the side walls disclosed by Frondoza in order to achieve the most effective ratio of permeable area to non-permeable area.

2) Claims 1, 3-7, 10-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feygin (US 6315957) in view of Robinson (US 6890740).

Feygin discloses an apparatus for intermixing small objects with a liquid comprising a plurality of receptacles (Figure 2:222) having a lower portion (Figure 2:226) that is permeable to permit the flow of liquid therethrough. A vessel (Figure 3:330) is additionally provided for containing a solution. The receptacles are repeatedly inserted into the solution held by the vessel in order to allow the solution to permeate through the pores located at the lower portions of the receptacles. The pores are sized so that they allow the passage of fluids, but not the passage of the small objects. This is disclosed in column 1, line 58 to column 2, line 38 and column 3, line 15 to column 4, line 19. Means for repeatedly moving the receptacle in and out of the vessel are described in column 4, line 53 to column 5, line 21 and in Figure 5. Feygin, however, does not expressly indicate that a portion of the side walls of the receptacle is not permeable.

Robinson discloses an apparatus for intermixing objects and a liquid comprising at least one receptacle (Figure 2:24) having sides and a bottom. In one embodiment (See Figure 1), the bottom and the sides of the receptacle are permeable. In another embodiment (See Figure 2), only the bottom of the receptacle is permeable. This is disclosed in column 3, lines 10-35.

Feygin and Robinson are analogous art because they are from the same field of endeavor regarding filtering mechanisms.

At the time of the invention, it would have been obvious to modify the apparatus of Feygin so that the receptacle includes a side wall portion that is permeable and a side wall portion that is not permeable. Frondoza already teaches the use of permeable side walls, and Robinson indicates that the use of impermeable side walls (in Figure 2) are known in the art as well. Therefore, it would have been apparent to modify the porosity of the side walls disclosed by Frondoza in order to achieve the most effective ratio of permeable area to non-permeable area.

3) Claims 1, 3-7, 10-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Feygin (US 6315957) or Frondoza (US 20050147959) each in view of Robinson (US 6890740), and further in view of Reeve (WO 9112079) and/or Valkirs (US 6348318).

The combination of Feygin and Robinson and the combination of Frondoza and Robinson are each described in the previous rejections above. In addition, Feygin discloses in column 6, lines 10-20 that affinity beads are used as small objects that facilitate a reaction with the solution as it moves through the permeable bottom of the receptacle from the vessel. Feygin and Frondoza, however, do not expressly state the use of a liquid solution that is a lysate containing proteins that become bound to the affinity beads when the solution and the affinity beads are intermixed.

Reeve discloses a method of purifying proteins. Reeve indicates on pages 4-6 that it is known in the art to remove proteins from a cell lysate by allowing them to bind to the surfaces of a plurality of affinity beads.

Valkirs discloses a method that involves the use of affinity beads that selectively bind to protein analytes in solution. The surfaces of the beads are covered with a moiety that attaches to analytes in order to form a target complex. The beads can then be removed from the solution as a means by which to obtain a purified product. This is disclosed in column 1, line 52 to column 2, line 52.

Feygin, Frondoza, Reeve and Valkirs are analogous art because they are from the same field of endeavor regarding filtering and protein purification systems.

At the time of the invention, it would have been obvious to use the devices proposed by Feygin and Frondoza in order to purify protein analytes in a lysate solution. Feygin already teaches that the device is capable of allowing particles in a solution to move through the porous bottom of the receptacle in order to interact with solid support beads. Therefore, one skilled in the art would have been fully capable of implementing the ideas regarding protein purification disclosed by Reeve and/or Valkirs in order to create a system in which the receptacle is allowed to interact with a lysate solution and remove protein targets. Absent a showing of criticality, it would have been obvious to utilize the affinity beads disclosed by Feygin as a means by which to bind to proteins in a lysate that are allowed to filter through a permeable barrier, especially since Reeve and Valkirs indicate that this is an effective process that is known in the art.



*Response to Arguments*

In response to Applicant's remarks, all previously made rejections under 35 U.S.C. 112 in the most recent Office Action (8/7/07) have been withdrawn.

Applicant's arguments filed 22 October 2007 with regard to the 35 U.S.C. 103 rejections involving the combination Feygin with Robinson and the combination of Frondoza with Robinson have been fully considered but they are not persuasive.

*Applicant's principle arguments are*

*(a) The Frondoza reference merely shows an insert component having at the bottom of each well a porous screen. Frondoza does not indicate that the screen is extended to a part of the side walls. Feygin only discloses a filter pocket plate that is permeable throughout. Robinson shows two configurations for his apparatus, either as a single mesh that is permeable throughout (Figure 1) or as a barrier plate in which the walls of the barrier plate are not permeable. Accordingly, no reference presented shows a single embodiment in which a receptacle is permeable on the bottom and partially permeable along at least one side.*

In response to Applicant's arguments, please consider the following comments.

Clearly, the Feygin, Robinson and Frondoza when taken together show that it is known in the art to provide permeable areas either across the entirety of a receptacle or at the bottom of a receptacle. It would have been obvious to extend the permeable areas of Frondoza in order to provide a screen at the side walls, and it would have been obvious to reduce the area of the permeable areas along the side walls of Feygin. The question is, however, to what extent? Robinson only teaches embodiments in which the changes are absolute. Figure 2 shows an

embodiment in which all of the permeable side wall areas have been removed, and Figure 1 shows an embodiment in which a screen has been added to the entirety of the side wall area.

Regardless, it is entirely within the purview of one of ordinary skill in the art to modify an invention according to the teachings of a reference, but not necessarily to the absolute extent disclosed by that reference. One of ordinary skill in the art would have understood that the advantages for adding permeable areas along the side walls of Frondoza's receptacle could still be obtained through a partial addition of a screen. Likewise, one of ordinary skill in the art would have recognized that the advantages of adding impermeable areas along the side walls of Feygin's receptacle could still be obtained through a partial removal of the screen. Side walls constructed from impermeable materials are likely more rigid than a porous screen and therefore work to increase the structural strength of the receptacle. Impermeable materials are also beneficial for encouraging the separation of intermixed objects only at designated areas of the receptacle. Side walls constructed from almost exclusively from permeable material are more effective in separating intermixed objects quickly and thoroughly because the increased area of the screen. One of ordinary skill in the art would have been able to consider these relative advantages and alter the apparatuses of Frondoza and Feygin in order to construct side walls that have ratios of permeable to impermeable area that are appropriate for a specified procedure.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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